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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,474	11/28/2003	Jacan Jung	13010-02USA	1022

35736 7590 08/24/2004

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,474	JUNG ET AL.	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A mere arrangement of printed matter is not within the statutory classes. See *In re Miller*, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); *Ex parte Gwinn*, 112 USPQ 439 (Bd. App. 1955); and *In re Jones*, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967)..

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claims 10 and 11 it is unclear what is considered to be the invention in that no steps are included in the method. Although unclear, the claims have been reviewed by the examiner as best understood at this time in order to continue with the examination.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3736

4. Claims 1, 8, 9, 10, 11, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,883,068 to Dechow.

In regards to claims 1, 8, 9, 10, 11, 13 and 17, Dechow discloses a device for collecting samples including at least one collection protrusion (16) comprising at least one tip (16a); at least one pad (18; Col. 2, line 52) for contacting the tip; and a storage area (17). The device is made of plastic (Col. 3, line 47). The sample comprises nucleic acid (Col. 1, lines 4 – 6). The storage area is fitted with tubing (16). Written instructions for using the device can be seen at Col. 3, lines 12 – 22.

5. Claims 1, 2, 4 – 13 and 19 - 21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,308,580 to Clark.

In regards to claims 1, 2, 4 – 13 and 19 - 21, Clark discloses a device for collecting samples including at least one foldable collection protrusion (24) comprising at least one tip (42); at least one pad (16) for contacting the tip (Col. 4, lines 14 – 17); and a storage area (Col. 2, lines 67 – 68) capable of storing a solid sample. The tip is a wick, spoon, pick or swab. Clark discloses a cap (52). The cap is disclosed as being connected to the device (Figure 3), detached from the device (Figure 4), and slidably encloses the device (Col. 4, lines 39 – 60). The device is made of plastic (Col. 4, line 34). The sample comprises nucleic acid (Col. 3, lines 24 - 29). Written instructions for using the device can be seen at Col. 4, lines 2 – 17.

6. Claims 1 – 3, 8, 10 – 14 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,766,962 to Childs et al.

In regards to claims 1 – 3, 8, 10 – 14 and 21, Childs et al. discloses a device for collecting samples including at least one foldable (Col. 5, lines 3 – 5) collection protrusion (5) comprising at least one tip (9); at least one pad for contacting the tip (Col. 5, lines 8 - 9); and a storage area (13). The tip is a wick, spoon, pick or swab (Col. 5, lines 65 – 67). The pad comprises chemical

Art Unit: 3736

preservatives or enzyme inhibitors . The device is made of plastic (Col. 4, lines 54 - 55). Written instructions for using the device can be seen at Col. 5, lines 3 - 9. The storage are is coated with a chemical preservative or enzyme inhibitor (Col. 6, lines 54 - 57).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,883,068 to Dechow in view of U.S. Patent No. 6,602,205 to Erickson et al.

In regards to claim 18, Dechow discloses a device for collecting samples including a tubing (16), but fails to disclose the tubing being capillary tubing. Erikson et al. teaches a device for collecting samples having a capillary tubing (12). It would have been obvious to one having ordinary skill in the art to modify the tubing as disclosed by Dechow to be a capillary tubing as taught by Erikson et al. in order collect the sample with minimal pain (Col. 5, lines 50 - 53).

9. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,883,068 to Dechow in view of U.S. Patent No. 4,370,987 to Bazell et al.

In regards to claims 15 and 16, Dechow discloses a device for collecting samples including a storage area comprising a pre-evacuated chamber (17; Col. 2, lines 53 - 55). However, Dechow fails to disclose the storage area being fitted with a syringe having unidirectional piston. Bazell et al. discloses a device for collecting samples including as a storage area a syringe having unidirectional piston (Col. 3 lines 55 - 59). It would have been obvious to one having ordinary skill in the art at

Art Unit: 3736

the time the invention was made to modify the pre-evacuated storage area as disclosed by Dechow to include a syringe having a unidirectional piston as taught by Bazell et al. in order to adjust the vacuum in the storage area for collecting different amounts of sample (Col. 1, lines 33 – 36).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



JMLF
August 23, 2004



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